

**INDEPENDENT REGULATORY REVIEW COMMISSION  
PUBLIC MEETING MINUTES**

10:00 A.M.

Thursday, September 15, 2016  
14<sup>th</sup> Floor Conference Room  
333 Market Street

**I. CALL OF THE MEETING**

The September 15, 2016 public meeting of the Independent Regulatory Review Commission (Commission) was called to order by Chairman Bedwick at 10:03 a.m. in the 14<sup>th</sup> Floor Conference Room, 333 Market Street, Harrisburg, PA.

Commissioners Present:      George D. Bedwick, Chairman  
   John F. Mizner, Esq., Vice Chairman  
   Dennis A. Watson, Esq.

Telephone:                      Murray Ufberg, Esq.

Absent:                              W. Russell Faber

**II. APPROVAL OF THE AUGUST 18, 2016 PUBLIC MEETING MINUTES**

Chairman Bedwick asked for a motion for approval of the August 18, 2016 public meeting minutes, as submitted. Commissioner Watson made the motion and Vice Chairman Mizner seconded, and the motion passed 4-0.

**III. NEW BUSINESS**

**A.      DEEMED APPROVED**

**1. No. 3085 Bureau of Professional and Occupational Affairs #16A-6516: Schedule of Civil Penalties - Physical Therapists and Physical Therapist Assistants**

**B.      ACTION ITEMS**

**1. No. 3063 Department of Community and Economic Development #4-95: Industrial Housing and Components**

James Smith, Regulatory Analyst, said the regulation is a general update of existing regulations to conform to various amendments made to the Industrialized Housing Act by three separate acts as well as current industry practices. He said the amendments address general provisions, scope, standard certification, third party agency fees, and administrative provisions. Mr. Smith also said the Department of Community and Economic Development (DCED) has both held an advance notice of final rulemaking and tolled the final regulation. He noted a

public comment received from the Pennsylvania State Association of Township Supervisors saying the regulation would not impose any additional requirements on them.

Jill Busch, Deputy Chief Counsel, Mark Conte, Division Chief, Housing Standards Division, and Lisa Maiorana, Assistant Counsel, DCED, were present to answer any questions.

Chairman Bedwick said the cooperative effort was “extremely good” to make the regulation non-controversial. Vice Chairman Mizner agreed.

Chairman Bedwick made a motion for approval. Vice Chairman Mizner seconded, and the motion passed 5-0, with Commissioner Faber voting by proxy.

## **2. No. 3084 State Board of Physical Therapy #16A-6515: Continuing Education Enforcement**

Corinne Brandt, Regulatory Analyst, said the regulation establishes disciplinary action on physical therapists and their assistants who fail to complete the required amount of continuing education (CE) during the applicable biennial renewal period. She noted that no comments on the final regulation were received.

Thomas Blackburn, Senior Counsel in Charge, Department of State, was present to answer any questions.

Mr. Blackburn said the rulemaking is a companion to regulation #3085. He said the State Board of Physical Therapy is attempting to change the method by which continuing education requirements are enforced by taking advantage of the streamlined Act 48 process rather than the “detailed process of filing orders to show cause.”

Chairman Bedwick asked about the Preamble noting people could mistakenly certify they have completed required hours and voiced concern with allowing three offenses before discipline because of the potential to encourage licensees to attempt to get away with violating the regulation. “When is enough, enough?” he questioned. Mr. Blackburn said licensees could roll the dice because of the system but said the rulemaking would not affect that. He emphasized that discipline still occurs each of the three times and that they would have to make up the CE. Mr. Blackburn also said the prosecution still has discretion to file additional charges, such as attaining licensure by fraud. “I believe what we’re doing is getting to the same end point as we do right now,” he explained. “However when we get to that point the licensee will be paying the appropriate civil penalty and making up whatever the deficiency is.”

Chairman Bedwick expressed concern with allowing licensees to be deficient 20 hours and asked for an example of where someone would be as such without intentionally violating the regulation. Mr. Blackburn said some pre-approved CE providers offer courses that licensees believe are approved, worth 16-20 hours, but then turn out not to be. He said 20 hours could be an honest mistake. Chairman Bedwick asked how physical therapists could know which are approved. Mr. Blackburn said there is no way to be 100 percent certain that pre-approved CE courses will meet the requirements. Chairman Bedwick said it seems like a crapshoot when

taking courses. Mr. Blackburn agreed there is that risk but said a prosecutor can use discretion if the course was valuable and was eventually approved.

Vice Chairman Mizner asked what the retrospective approval would be based on. Mr. Blackburn said that during an audit process for licensees the staff will compare documentation from the course to the statutory requirements. Vice Chairman Mizner asked for clarification that when one pays for a course they don't know if it will be approved or how many credits it will be. Mr. Blackburn said there is no guarantee when signing up with a pre-approved provider that it will count for credit. Vice Chairman Mizner compared the process to the certainty and practical side of taking Continuing Legal Education (CLE) as a lawyer and said the system seems "screwed up and unfair to the licensees." Mr. Blackburn agreed there is risk regarding pre-approved providers.

Chairman Bedwick asked why the State Board of Physical Therapy takes the approach it does considering that risk. Mr. Blackburn said they have just begun CE in 2012 and allow pre-approved providers because of the difficulty of reviewing the large number of courses in advance. Chairman Bedwick said they are still reviewing all the courses, just deferring some until after the fact. Mr. Blackburn said that is true for only the ones that have been audited. He explained that a pre-approved course is only reviewed if being relied upon to demonstrate compliance which he said usually comes about during an audit.

Commissioner Watson said there is a similar process for lawyers and CLE's when licensed in several states. Each state reviews if the CLE obtained can be used to fit its own criteria for credit.

Chairman Bedwick asked if submission for approval is required to get credit. Mr. Blackburn said submission is required to receive credit. Chairman Bedwick said the system seems "a bit crazy," but added that Mr. Blackburn's answers satisfied his questions.

Lastly, Chairman Bedwick noted that Commissioner Faber's proxy vote was submitted without the ability to hear the answers to the previous questions. "His vote should be taken in that light," he opined.

Vice Chairman Mizner made a motion for approval. Commissioner Ufberg seconded, and the motion passed 4-1, with Commissioner Faber dissenting by proxy.

### **3. No. 3062 State Board of Medicine #16A-4943: Prosthetists, Orthotists, Pedorthists and Orthotic Fitters**

Ms. Brandt said the regulation implements the creation of new classes of licenses, as mandated by Act 90 of 2012, which requires the State Board of Medicine (Board) to issue licenses to prosthetists, orthotists, pedorthists, and orthotic fitters and regulate the practice of these licensees and to discipline them. She noted a comment was received from the Pennsylvania Orthotic and Prosthetic Society requesting changes to credentialing language and the inclusion of grandfathering language.

Cynthia Montgomery, Regulatory Counsel, Department of State, and Peter Kovach, Board Counsel, were present to answer any questions.

Ms. Montgomery said the Board conducted a great amount of outreach to the regulated community from the beginning, with numerous meetings and drafting language with all parties seated at the table. “We believe the final rulemaking has answered as many of the concerns as we can consistent with the statutory language.”

Jonathan Vipond, Attorney with Buchanan, Ingersoll, and Rooney, and representing Pennsylvania Orthotic and Prosthetic Society, said the regulation has come a long way and is almost there, but expressed concern with ensuring the best possible chance for those who are fitted with orthotic or prosthetic devices. He asked that educational requirements not only be for credentialed organizations and those approved by the National Commission on Orthotic and Prosthetic Education (NCOPE) and Institute for Credentialing Excellence (ICE), but also expand to other credentialing organizations. He said it should not be limited to those two organizations, but rather include any organization approved by the Board to be sufficient for educational purposes. On the grandfathering provision, Mr. Vipond said national certification at any time, if so certified in 2012, should be included. He said the process has been laborious, but expressed desire to help everyone do the job well.

Chairman Bedwick said, from the Commission’s standpoint, their participation is appreciated. He asked for clarification on the grandfather issue. “Could I have been certified in 1990 and never certified again?” he asked. Mr. Vipond said that is his understanding of the provision. “If you ever held national certification prior to the Act, and were out there practicing, that’s enough for you to go forward,” he said.

R. Jeffrey Hedges, a health care consultant representing 981 independent pharmacies around the Commonwealth, said when original legislation was drafted in 2014, pharmacies were excluded from orthotic and prosthetic, specifically diabetic shoes, at the national level. He said when state licensure comes up and is passed it is then passed to Medicare and Medicaid, specifically to the national supplier clearinghouse. He said they take state laws explicitly as written. Mr. Hedges then explained this results in certain states having to go back to permit pharmacists to be recognized as an authorized provider. He then said even though the state scope of practice will state the pharmacist can dispense any written prescription, medication, or device, the state regulations are what the national clearinghouse will review. Mr. Hedges clarified that this requires states to go back and allow pharmacists to provide diabetic shoes. “My concern is, if we don’t add the pharmacy definitions into the regulation, from past history we will see the national supplying clearinghouse actually prohibit pharmacists in this state from dispensing diabetic shoes.” He then referenced movements to move all orthotics that are not custom-made to off the shelf, which he said would take away orthotic fitters’ whole career field due to insurance companies and Medicaid following the federal rule.

Vice Chairman Mizner asked how state law deals with the issue. Mr. Hedges said state law states pharmacists may dispense, with a written prescription, any medication or device. Vice Chairman Mizner asked if the regulation would conflict with that. Mr. Hedges said yes, it would supersede that from the federal standpoint. Vice Chairman Mizner asked if Mr. Hedges has

talked to the Board about adding additional language. Mr. Hedges said he submitted comments twice, with the Board stating they did not see how such results could be possible.

Chairman Bedwick asked what the licensee statute says. Mr. Hedges said it does not cover the issue, and said language in the actual act is omitted from the regulation proposed today. Chairman Bedwick asked if the legislation is in the act itself. Mr. Hedges said they are asking for the language from the act to be added to the regulation. Chairman Bedwick asked if Mr. Hedges sees the federal government using the regulation to override the statute. Mr. Hedges said yes, specifically referencing the competitive bid process as yielding devastating results.

In response to Mr. Hedges' statements, Ms. Montgomery said the Board believes the statute provides that "nothing in this section shall prohibit an individual, including but not limited to pharmacist, podiatrist, or physician from engaging in the practice for which that individual is licensed . . . or to act within the scope of that license, registration, or certification." She said that pharmacists would be able to continue to do everything they did previously within the scope of their license, which would include Mr. Hedges' area of concern.

Vice Chairman Mizner said the federal government position referenced by Mr. Hedges could be a potential class action lawsuit. Ms. Montgomery said the Board does not regulate reimbursement or billing but said the statute trumps the regulation, and said the federal government could not ignore the plain language of the statute to make those decisions. Vice Chairman Mizner asked if a pharmacist will be able to continue to serve their diabetic patients as they always have if the regulation was passed. Ms. Montgomery said yes. She said the language was not in the regulation only because the board does not regulate pharmacists.

In response to Mr. Vipond's statement, on certification for education, Ms. Montgomery said language in the regulation includes certifying bodies approved by the Board. "Any organization that meets those requirements, including those listed, we did add that." In reference to the education requirement, she said the Board continues to require orthotists, pedorthists, and prosthetists to ensure the education is high quality, and therefore did not make a change.

Chairman Bedwick asked if the Board's position is that statutory language provides the Board with discretion to determine what will be approved and what will not. Ms. Montgomery said yes.

On the grandfathering provision, Ms. Montgomery said various language in the bill states they would have had to apply by July 2015 to get the grandfathered license. "So all of these people should already be licensed," she said. "The grandfather provision has already been implemented because the statute says 'beyond this date you can't practice without a license.'"

Chairman Bedwick asked if anyone has applied and been denied licensure based on that provision. Ms. Montgomery said she is not aware of any. She said anyone denied licensure would be offered a hearing to demonstrate they meet qualifications.

Chairman Bedwick said he understands Ms. Montgomery's argument on language regarding the grandfathering provision. However, he asked if the "on or before" line becomes

superfluous language under her interpretation. Ms. Montgomery said the provision “is now basically sunset.” She said 623 out of 869 licensees got their license through the grandfather provision, and she is not aware of any that were denied. “Going forward, there is no need to worry about the grandfathering provision because we’re not going to be granting additional licenses under that section because that section expired by limitation in the statute.”

Chairman Bedwick asked Mr. Vipond if he is aware of anyone who has applied and been denied. Mr. Vipond said he is not, but just wanted to keep the possibility open. “If there is a mechanism through the informal and occasional process that would probably be satisfactory.”

Mr. Hedges asked if the statute or regulation is what is sent out to all agencies. Ms. Montgomery said the regulation is what is published in the *Pennsylvania Bulletin*. Mr. Hedges said the original bill was based on Ohio’s legislation. He then said Ohio had to go back and change the statute to cover pharmacists after the fact because the regulation was what the national supplier clearinghouse reviewed. Mr. Hedges said specific writing regarding this issue is needed to prevent the exclusion from occurring in Pennsylvania. Vice Chairman Mizner said the law is published and available, and that the statute will control a regulation if it is in violation.

Chairman Bedwick said a regulation cannot override the statute. He asked Ms. Montgomery if the State Board of Pharmacy could clarify the issue if Mr. Hedges was to approach them. Ms. Montgomery said she cannot speak to the State Board of Pharmacy’s position but they could certainly be approached.

Vice Chairman Mizner made a motion for approval. Commissioner Watson seconded, and the motion passed 5-0, with Commissioner Faber voting by proxy.

#### **IV. OTHER BUSINESS**

##### **Approval of Vouchers**

Commissioner Watson made motions to approve vouchers and expenses for the period July 22, 2016 through August 18, 2016. Commissioner Ufberg seconded, and the motions passed 4-0.

#### **V. DATE AND PLACE OF SUBSEQUENT MEETING**

Chairman Bedwick announced the next public meeting is scheduled for Thursday, October 20, 2016, at 10:00 a.m. in the 14<sup>th</sup> Floor Conference Room, 333 Market Street, Harrisburg.

#### **VI. EXECUTIVE SESSION ANNOUNCEMENTS**

Chairman Bedwick announced that no executive session would be held.

## **VII. ADJOURNMENT**

Chairman Bedwick announced the meeting adjourned at 11:04 a.m.